PRODUCT GUIDE SHUKLA SPINE

Universal Spinal Screw Removal Solution

#13-14
Systems 13 and 14 of 15





Universal Spinal Screw Removal Solution

System Name: SHUKLA Spine-CTL v3

Primary Use

The SHUKLA Spine Cervical, Thoracic, and Lumbar system (Spine-CTL), is a family of systems designed to remove spinal screws, locking caps, rods, and plates from any cervical, thoracic, or lumbar implant system. Across dedicated cervical & thoracolumbar driver systems, it contains more than 130 drivers compatible with standard configurations, as well as more than 40 proprietary implant systems.



System History

The very first SHUKLA Spine set debuted back in 2000, but it did not contain an option for cervical implant or screw removal - this was added in as an option during a later version. The first Spine-Cervical set came out in 2005 thanks to the efforts of both Shukla Medical Product Development Manager as well as invaluable input from surgeons. The release of the Spine-Cervical (Spine-C) in addition to the existing Spine-Thoracolumbar (Spine-TL) made the total capabilities of Shukla's Spine family truly universal.

The first Spine-CTL system didn't come around until after the Spine-C debuted. In 2018, the newest version of our Spine systems released, making an already amazing set even better and more comprehensive.

2005: Version 1 Introduced

2009: Version 2 Introduced

- · Case Redesign
- More Drivers
- More Proprietary Implant Drivers

2018: Version 3 Introduced

- Helicopter Sockets
- · More Drivers
- More Proprietary Implant Drivers
- · Upgraded Case Redesign

Key Benefits

- More than 130 drivers specifically designed for spinal implants and screw removal across the entire spine.
- More than 40 proprietary implant removal drivers make the removal of specific company's proprietary screws faster and simpler.



Small sample of how diverse spinal drivers can be.

- A Breaker Bar is included for applying extra torque when needed.
- Four Extensions are provided, ranging from four to twelve inches in length. These are perfect for both anterior and lateral procedures.
- Ratcheting inline handle speeds up screw removal as well as reduces surgeon hand fatigue.



- Saddle and Blade drivers allow for Monoaxial Screw compatibility.
- Helicopter sockets for when a spinal screw or cap strips out or cannot be removed. By cutting
 the rod on either side of the implant tulip, the entire construct can be removed.
- Specially engineered vertical case with a tiered design for easy to recognize placement of the drivers no matter the row. Easy-to-read identification for each driver available on the case itself as well.

Universal Shukla System Benefits for Better Patient Outcomes

Less Time Spent in O.R.

- Reduces risk of infection to patient
- Reduces time spent under anesthesia
- Reduces cost to the hospital

Universal Designs

- Less prep time for surgeons
- · Less space taken up in the O.R.
- Reduces need for other systems or tools

Ergonomic Design

- Reduces surgeon stress
- · Reduces surgeon fatigue
- Better grip/reduces slippage

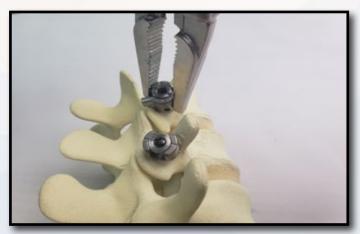
Comprehensive Design

- Addresses all known challenges
- Tools ensure surgery is a success
- Provides backup solutions during surgery

Alternative Method Comparison

You could call in reps from different companies to try and swing by to try to bring the proper set of tools to the O.R., or you can get a Shukla Spine-CTL set and be equipped to remove anything that comes your way immediately and without delay. Our Spine-CTL is so overstocked with every possible driver you can think of. It is the single most universally compatible set on the market.

Since our helicopter sockets are patented, other spinal screw removal sets do not have the same capabilities that we can offer. Surgeons are often faced with the choice of either waiting on the proper rep, closing up the patient and trying again later, or using vise grips/pliers to try and manually remove the screw. This is the same as what our helicopter sockets do. But the SHUKLA Spine does it elegantly, less dangerously, and with more of a guarantee to succeed.



The Vise Grip method, an attempt to emulate what a helicopter socket does easier and more effectively.

Return On Investment Justification

According to a study published in *JAMA* Surgery, the cost of one minute in an O.R. can vary anywhere from \$36 per minute to \$100 per minute, with the average cost of a minute in the O.R. at a staggering \$66! Taking just the lowest estimate of time savings, the savings per surgery can be estimated at 75 minutes x \$36 per minute = \$2,700.

Think about just how often your surgeons or your hospital does a spinal revision surgery. All spine surgeons deserve the best tools at their disposal. How much time and money is wasted if even a single driver is not prepped and sterilized in the O.R.? A SHUKLA Spine-CTL sells for \$35,000, which means the system recoups its cost in, at the most, 16 hours of saved O.R. time. Considering how often the Spine-CTL's universal compatibility comes into play, that won't take long at all.

When You Don't Have It

Every surgeon deserves the best when they step into the O.R. to work a case. Think back on the times when you discovered that you did not have the proper drivers for a screw,or the times when you couldn't get out a screw due to the locking cap. How much extra time was spent trying to find workarounds? How many hours over how many surgeries?

If your hospital is on the fence about getting a system, one of our Shukla reps will be glad to provide information of our SHUKLA Spine-CTL and bring one to you for a demonstration. A successful surgery and a closed case are closer than you think.

You might not always *need* the full universal nature of our Spine-CTL system, but you will definitely be glad you had it when the time comes.

How We Compare

Most orthopaedic implant manufacturers provide revision/extraction tools suited *only* for their own implants. Even suppliers that claim to offer extraction sets basically have an assortment of tools thrown together as an afterthought. For Shukla Medical, *extraction is what we do*. Our engineers design truly universal tools to help remove any implant/hardware out there, making our competition essentially nonexistent. Our patented designs are revolutionizing the art of revision surgery; we proudly stand alone. We have still tried to provide a comparison to other systems on the market.

There are several other spinal screw removal systems on the market and even though they occasionally loan their sets out free of charge, surgeries have to be adjusted based on their availability. Not only is that more inconvenient but they only offer drivers and sockets compatible with their own implants.

Hospitals worldwide are upgrading to the SHUKLA Spine for many obvious reasons. With over 130 available drivers, the SHUKLA system is truly universal; every driver and socket combination we can think of is included. We also include many proprietary drivers designed for specific screws or implants. No other manufacturer that supplies screw removal options includes such proprietary drivers. Other systems not only cost significantly more than ours but are no match to the SHUKLA Spine.

PATENT

Helicopter Socket

The SHUKLA Spine systems all share our patented Helicopter Sockets. Our engineering team worked tirelessly to provide surgeons with an intelligent, effective system.

HELICOPTER SOCKETS

Available in three different sizes, engineered to fit any type of pedicle screw construct you could possibly come across.







Small

Medium

Large

Engineered to fit the spine rod - once inserted, the rod will not slip or pull off. The helicopter sockets work with all spine rods up to 6.35 mm in diameter.

Made with medical grade stainless steel, the helicopter sockets also have a ball detent that allows for quick-attach capability with our range of Extensions.

For spinal systems that use a PEEK Rod, our helicopter sockets are still compatible. However, since torque must be limited in that situation, only the Ratcheting T-Handle should be used, **not** the breaker bar.

Attention to Detail

The patented helicopter sockets possess a beveled edge on their socket openings. This small design choice improves access for the spine rod, as well as requiring less tissue removal under the rod. This is generally very difficult to accomplish, but our copter sockets make it seem effortless.

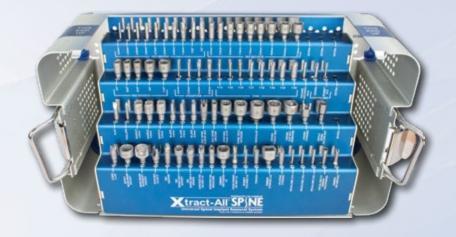
The Spine-CTL system boasts the same attention to the small details as the Spine-C and Spine-TL sets. The case is now vertical, so the drivers are displayed upright and are labeled clearly on the case as well as on each driver itself for simple identification. The tiered driver displays take up minimal space on the table, keeping surfaces clear and organized. Each driver is marked with a number that identifies its slot placement. Corresponding numbers are displayed clearly on the case itself, making it easy to find what you need and easy to put it back.

All of our drivers are designed to be used during Minimally Invasive Surgery as well, making the utility of our Spine family of systems truly incredible.



The Spine-C case boasts over 50 drivers as well as more than 15 proprietary drivers to help make revision surgery easier.

The Spine-TL case contains over 75 drivers and more than 25 proprietary drivers to help make revision surgery go smoothly.



The Spine-CTL set not only has long low profile drivers to help you reach anything that needs reaching, but it also comes with four different sizes of driver extensions. With sizes ranging from four to twelve inches in length, there won't be a screw or construct around that you won't be able to reach.



Our Long Nose Locking Pliers are low profile in order to get inside an incision. They are vise grip style to intuitively adjust and lock quickly.



Our Rod Grippers are also low profile and fully adjustable with locking capabilities. Removing the rod can sometimes be difficult with regular pliers on account of the rod being smooth and round and the plier jaws being flat. Our Rod Grippers fix that potential issue before it even occurs.







System Name: SHUKLA Spine-Plus

The SHUKLA Spine-Plus is our full Spine-CTL family of systems, with a complete second case of the instrumentation.

Thanks to the Spine-Plus including two instrumentation trays instead of just one, multiple spinal revisions can be scheduled in a day without bottlenecking flow because of low availability. You could run spine surgeries back to back if need be.

Perform revision after revision before having to finally submit your trays to sterilization. Our SHUKLA Spine-Plus is so comprehensive that direct comparisons to our competition don't seem fair. The sheer amount of drivers at your disposal, coupled with the second tray filled with all the instrumentation you would need, mean that no matter what cases you work on, you can find success.

Drastically reduce the wait time of getting systems or instrumentation back from the SPD by having a backup tray with you.

Return On Investment Justification

Like previously mentioned, the *JAMA* Surgery survey showed that the cost of one minute in an O.R. can rnage from \$36 per minute to \$100 per minute, with an average of \$66! Like the Spine-CTL before it, if you take just the lowest estimate of time savings, the savings per surgery can be estimated at 30 minutes x \$36 per minute = \$1,080 for the Spine-Plus as well.

If you are a hospital or a surgeon that performs spinal revision surgeries, you know just how important being efficient with your time can be. Why waste your time waiting on the sterilization process to finish? With a second set of instrumentation, you can go from case to case with no down time. A SHUKLA Spine-Plus sells for \$40,000, which means the system recoups its cost in, at the most, 19 hours of saved O.R. time. Considering how much more universal and comprehensive our spine sets are compared to the competition, the justification is easy to see.

Instrumentation Case

Each of the two instrumentation cases contain the following components:

- Ratcheting T-Handle
- Ratcheting Inline Handle
- · Breaker Bar
- Hudson Adapter
- · Helicopter Sockets (Small, Medium, Large)
- Double Open Ended Wrenches (7/32" & 9/32", 1/4" & 3/8", 5 mm & 7 mm, 6 mm & 10 mm)
- Long Nose Locking Pliers
- Rod Gripper
- Driver Extensions (4", 6", 8", 12")

Since you get two cases in the SHUKLA Spine-Plus, you get double of everything just mentioned!







Components List

	Component List				
Std Qty	ID #	Part Number	Description		
1		HD233	THandle, Ratcheting, Square, 1/4"		
1		HD239	Handle, Breaker Bar		
1		MHRS0311	Handle Assy, In-Line, Ratcheting, Square, 1/4"		
1		SAD005	Adapter, 1/4" Square to Hudson		
1		SCS044	Case, Helicopter Socket System		
1		SCS045	Lid, Helicopter Socket System		
1		SCS036	Case, Spine System, Instruments		
1		SCS039	Lid, Spine System, Instruments	\Box \Box \Box	
1		SDR813	Driver Assy, Socket, Helicopter, Small	nst	
1		SDR814	Driver Assy, Socket, Helicopter, Medium	T = 1	
1		SDR815	Driver Assy, Socket, Helicopter, Large	ne	
1		SWR003	Wrench, Double Open End, 7/32" & 9/32"	Instrumentation	
1		SWR004	Wrench, Double Open End, 1/4" & 3/8"	Tio	
1		SWR005	Wrench, Double Open End, 5 mm & 7 mm	_	
1		SWR006	Wrench, Double Open End, 6 mm & 10 mm		
1		SWR008	Pliers, Long Nose, Locking, 9"		
1		SWR009	Pliers, Rod Gripper		
1		SXN007	Extension Assy, 4"		
1		SXN008	Extension Assy, 6"		
1		SXN009	Extension Assy, 8"		
1		SXN010	Extension Assy, 12"		
1		SCS035	Case, Thoracic & Lumbar Spine System, Drivers		
1		SCS038	Lid, Thoracic & Lumbar Spine System, Drivers		
1	5	SDR705	Driver Assy, Male, Hex, 3 mm		
1	7	SDR707	Driver Assy, Male, Hex, 3.5 mm		
1	8	SDR708	Driver Assy, Male, Hex, 4 mm		
1	9	SDR709	Driver Assy, Male, Hex, 4.5 mm		
1	10	SDR710	Driver Assy, Male, Hex, 4.7 mm	╛╻	
1	11	SDR711	Driver Assy, Male, Hex, 5 mm	Ihoracic & Lumbaı	
1	12	SDR712	Driver Assy, Male, Hex, 6 mm	rac	
1	13	SDR713	Driver Assy, Male, Hex, 7 mm	ic a	
1	20	SDR720	Driver Assy, Male, Hex, 7/32"	$\neg \%$	
1	21	SDR721	Driver Assy, Male, Hex, 1/4"	l au	
1	26	SDR726	Driver Assy, Female, Hex, 5 mm	1ba	
1	27	SDR727	Driver Assy, Female, Hex, 5.5 mm] =	
1	28	SDR728	Driver Assy, Female, Hex, 6 mm		
1	29	SDR729	Driver Assy, Female, Hex, 7 mm		
1	30	SDR730	Driver Assy, Female, Hex, 7.5 mm		
1	31	SDR731	Driver Assy, Female, Hex, 8 mm		
1	32	SDR732	Driver Assy, Female, Hex, 9 mm		
1					

			Component List	
Std Qty	ID #	Part Number	Description	
1	34	SDR734	Driver Assy, Female, Hex, 11 mm	
1	41	SDR741	Driver Assy, Female, Hex, 1/4"	1
1	42	SDR742	Driver Assy, Female, Hex, 9/32"	1
1	43	SDR743	Driver Assy, Female, Hex, 5/16"	1
1	44	SDR744	Driver Assy, Female, Hex, 3/8"	
1	45	SDR745	Driver Assy, Female, Hex, 7/16"	
1	51	SDR751	Driver Assy, Male, Cruciform, 3 mm	
1	52	SDR752	Driver Assy, Male, Cruciform, 3.5 mm	
1	53	SDR753	Driver Assy, Male, Cruciform, 4.5 mm	
1	54	SDR754	Driver Assy, Male, Cruciform, 6 mm	
1	61	SDR759	Driver Assy, Male, Torx, T15]
1	62	SDR760	Driver Assy, Male, Torx, T20	
1	63	SDR761	Driver Assy, Male, Torx, T25	
1	64	SDR762	Driver Assy, Male, Torx, T27	
1	65	SDR763	Driver Assy, Male, Torx, T30	
1	66	SDR764	Driver Assy, Male, Torx, T40	
1	67	SDR765	Driver Assy, Male, Torx, T45	
1	68	SDR766	Driver Assy, Male, Torx, T50] , ,
1	73	SDR773	Driver Assy, Male, Square, 4 mm for Orthofix] [
1	76	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross	rac
1	77	SDR777	Driver Assy, Male, Pentalobe, S15] ic
1	82	SDR782	Driver Assy, Male, Flat Head, .250" Wide	\& I \&
1	83	SDR783	Driver Assy, Male, Phillips	Thoracic & Lumbar
1	84	SDR784	Driver Assy, Saddle, 4 mm] ਲੂ
1	85	SDR785	Driver Assy, Saddle, 5 mm] =
1	86	SDR786	Driver Assy, Saddle, 6 mm	
1	87	SDR787	Driver Assy, Blade, 4 mm	
1	88	SDR788	Driver Assy, Blade, 5 mm	
1	89	SDR789	Driver Assy, Blade, 6 mm	
1	100	SDR805	Driver Assy, Female, Dodecagon, for Outer Nut by Depuy Spine	
1	106	SDR811	Driver Assy, Male, 2-Prong, for Incompass by Zimmer	
1	120	SDR850	Driver Assy, Sleeve Nut, For Adv Spine	
1	121	SDR851	Driver Assy, Anchor, For Adv Spine	
1	122	SDR852	Driver Assy, Double Hex, 11 mm, For Synthes	
1	123	SDR853	Driver Assy, Octagon, For Spine Tech	
1	124	SDR854	Driver Assy, 4 prong, For Aesculap	
1	125	SDR855	Driver Assy, Female, Hex, 13.8mm, For Interpore Cross	
1	126	SDR856	Driver Assy, Female, Hex, Cap Nut Remover for Interpore Cross	
1	127	SDR857	Driver Assy, 2 Prong, For Interpore Cross	
1	128	SDR858	Driver Assy, Trilobe, Male, For 3-lok by Corin	
1	129	SDR859	Driver Assy, Female, For Moss-Miami by DePuy	
1	130	SDR860	Driver Assy, Female, Horse Shoe, For Moss-Miami by DePuy	

Components List

			Component List	
Std Qty	ID #	Part Number	Description	
1	131	SDR861	Driver Assy, 2 prong, For Click'X by Synthes	
1	132	SDR862	Driver Assy, Male, Square, For EBI	
1	133	SDR863	Driver Assy, Female, Flower Shaped, for Spinelink II by EBI	
1	134	SDR864	Driver Assy, Male, Flower Shaped, for Spinelink II by EBI	
1	135	SDR865	Driver Assy, Male, 4 prong, for Xia by Stryker Spine	_
1	136	SDR866	Driver Assy, Female, Hexalobe, for Xia III by Stryker Spine	뒫
1	137	SDR867	Driver Assy, Female, Heptagon, 1/2", for Silhouette by Zimmer	Thoracic & Lumbar
1	138	SDR868	Driver Assy, 4 prong, for Radius by Stryker Spine	ic d
1	139	SDR869	Driver Assy, Male, Pentalobe, for Polaris 5.5 by Biomet	1x
1	142	SDR872	Driver Assy, Male, 2-Prong, for Theken	m
1	143	SDR873	Driver Assy, Female, for Dynesys LIS by Zimmer	bar
1	144	SDR874	Driver Assy, Male, 3-Prong, for US Spine]
1	146	SDR876	Driver Assy, Male, Hexalobe, X15	
1	147	SDR877	Driver Assy, Male, Hexalobe, X20	
1	148	SDR878	Driver Assy, Male, Hexalobe, X25	
1	149	SDR879	Driver Assy, Female, Hexalobe, E7, for Pathfinder by Zimmer	
1		SCS034	Case, Cervical Spine System, Drivers	
1		SCS037	Lid, Cervical Spine System, Drivers	
1	1	SDR701	Driver Assy, Male, Hex, 2 mm	
1	2	SDR702	Driver Assy, Male, Hex, 2.25 mm	
1	3	SDR703	Driver Assy, Male, Hex, 2.5 mm	
1	4	SDR704	Driver Assy, Male, Hex, 2.75 mm	
1	5	SDR705	Driver Assy, Male, Hex, 3 mm	
1	7	SDR707	Driver Assy, Male, Hex, 3.5 mm	
1	8	SDR708	Driver Assy, Male, Hex, 4 mm	
1	16	SDR716	Driver Assy, Male, Hex, 7/64"	
1	17	SDR717	Driver Assy, Male, Hex, 1/8"	င္စ
1	18	SDR718	Driver Assy, Male, Hex, 5/32"	Cervical
1	19	SDR719	Driver Assy, Male, Hex, 3/16"	<u>2</u>
1	24	SDR724	Driver Assy, Female, Hex, 3.5 mm	
1	25	SDR725	Driver Assy, Female, Hex, 4 mm	
1	37	SDR737	Driver Assy, Female, Hex, 1/8"	
1	38	SDR738	Driver Assy, Female, Hex, 5/32"	
1	39	SDR739	Driver Assy, Female, Hex, 3/16"	
1	40	SDR740	Driver Assy, Female, Hex, 7/32"	
1	46	SDR746	Driver Assy, Female, Hex, 1/2"	
1	49	SDR749	Driver Assy, Male, Cruciform, 2 mm	
1	50	SDR750	Driver Assy, Male, Cruciform, 2.5 mm	
1	51	SDR751	Driver Assy, Male, Cruciform, 3 mm	

Component List				
Std Qty	ID #	Part Number	Description	
1	52	SDR752	Driver Assy, Male, Cruciform, 3.5 mm	
1	56	SDR756	Driver Assy, Male, Torx, T6	
1	58	SDR757	Driver Assy, Male, Torx, T8	
1	60	SDR758	Driver Assy, Male, Torx, T10	
1	61	SDR759	Driver Assy, Male, Torx, T15	
1	62	SDR760	Driver Assy, Male, Torx, T20	
1	63	SDR761	Driver Assy, Male, Torx, T25	
1	57	SDR767	Driver Assy, Male, Torx, T7	
1	59	SDR768	Driver Assy, Male, Torx, T9	
1	69	SDR769	Driver Assy, Male, Square, 2 mm for Orthofix	
1	70	SDR770	Driver Assy, Male, Square, 2.5 mm for Orthofix	
1	71	SDR771	Driver Assy, Male, Square, 3 mm for Orthofix	
1	72	SDR772	Driver Assy, Male, Square, 3.5 mm for Orthofix	
1	76	SDR776	Driver Assy, Male, Pentalobe for Interpore Cross	
1	77	SDR777	Driver Assy, Male, Pentalobe, S15	
1	80	SDR780	Driver Assy, Male, Flat Head, .110" Wide	
1	81	SDR781	Driver Assy, Male, Flat Head, .140" Wide) {
1	82	SDR782	Driver Assy, Male, Flat Head, .250" Wide	CET A ICAT
1	83	SDR783	Driver Assy, Male, Phillips	1
1	84	SDR784	Driver Assy, Saddle, 4 mm	
1	87	SDR787	Driver Assy, Blade, 4 mm	
1	95	SDR800	Driver Assy, Male, Star shaped, for Aesculap	
1	96	SDR801	Driver Assy, Male, U shape, unlock tool, for Alphatec	
1	97	SDR802	Driver Assy, Male, 2 prong, for Blackstone	
1	98	SDR803	Driver Assy, Male, Tri-Lobe, for Blackstone	
1	99	SDR804	Driver Assy, Male, 3 prong, for Cervive by Corin	
1	101	SDR806	Driver Assy, Male, Square, Unlock tool, For Interpore by Cross	
1	102	SDR807	Driver Assy, Male, Square, For Medtronic	
1	103	SDR808	Driver Assy, Male, 4 prong, for Stryker Spine	
1	104	SDR809	Driver Assy, Male, Flower Shaped, For Spinelink ACS by EBI	
1	105	SDR810	Driver Assy, Male, 3 pronged, for Cervi-Lok by Zimmer	
1	107	SDR812	Driver Assy, Male, 3-Prong, for Nex-Link by Zimmer	
1	145	SDR875	Driver Assy, Male, Hexalobe, X10	
1	146	SDR876	Driver Assy, Male, Hexalobe, X15	
1	147	SDR877	Driver Assy, Male, Hexalobe, X20	



Revolutionizing the Art of Revision Surgery

Shukla Medical designs and manufactures instrumentation for orthopedic implant extraction at our headquarters in St. Petersburg, Florida, USA. We are proud to be an *ISO 13485:2016* Certified company.

In 1998, aerospace component manufacturer S.S. White Technologies, Inc. acquired the Medical Products Division of Snap-On. S.S. White rebranded the medical division in 2007 to create Shukla Medical.

Today, Shukla Medical is the industry leader in orthopedic implant extraction tools. We are the only company to offer a comprehensive, truly universal orthopedic revision line for removing IM nails, hip and knee implants, spine hardware, and broken or stripped screws. Surgeons and industry leaders know: If Shukla can't get it out, no one can.

Contact us to learn more

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SHUKLA Surgical Tech Support 24 hours a day, 7 days a week 727-626-2771

When you have tried all known techniques to extract an implant or remove a screw but determine you need suggestions for alternate techniques, help is only a phone call away. We will quickly put you in touch with our Technical Experts who will suggest other solutions to use our tools.



SHUKLA Medical offers the best warranty in the industry. Every component in a SHUKLA extraction system is designed and manufactured by us. Every component in our extraction systems that is not a single-use* or a wear* component is warranted against manufacturing defects for the life* of the system. All other parts are covered for as long as the purchased version of the system is actively marketed by SHUKLA Medical.

*Please see our website for the complete explanation of these terms and full details on our warranty.