MAUDE database as of mid-July 2018				
Yellow = failure				
	BRAND	**DATE**	**Cross Ref of Cat**	**Event Description**
STRYKER SPINE-US	10MM X 6DEG X 11MM X 28MM	5/3/18	**Tritanium PL**	**inserting the pl cage with the correct inserter, it broke in the middle**
STRYKER ORTHOPAEDICS-CORK	10MM X 6DEG X 11MM X 28MM	5/2/18	**Tritanium PL**	**implant broke during a procedure. Part of the implant remains implanted in the patient. There was less than 20 minutes surgical delay**
STRYKER ORTHOPAEDICS-CORK	12MM X 6DEG X 11MM X 28MM	5/2/18	**Tritanium PL**	**broke in the middle of the cage**
STRYKER ORTHOPAEDICS-CORK	8MM X 0DEG X 11MM X 28MM	5/1/18	**Tritanium PL**	**fractured in a post op patient that received a l4-s1**
STRYKER ORTHOPAEDICS-CORK	9MM X 6DEG X 11MM X 23MM	4/19/18	**Tritanium PL**	**ct scan of a patient who had surgery about three months ago, the doctor confirmed that the cage was broken between the vertebral bodies.**
STRYKER ORTHOPAEDICS-CORK	10MM X 6DEG X 11MM X 28MM	4/11/18	**Tritanium PL**	**impacting the cage into disc space at l3/4, the cage broke**
STRYKER ORTHOPAEDICS-CORK	9MM X 6DEG X 9MM X 28MM	4/10/18	**Tritanium PL**	**upon insertion of the cage at the l5-s1 level broke in two pieces**
STRYKER ORTHOPAEDICS-CORK	7MM X 6DEG X 11MM X 28MM	4/3/18	**Tritanium PL**	**cage broke upon insertion in the patient**
STRYKER ORTHOPAEDICS-CORK	12MM X 0DEG X 11MM X 28MM	4/2/18	**Tritanium PL**	**the cage looked cracked on x-ray**

STRYKER ORTHOPAEDICS-CORK	9MM X 0DEG X 11MM X 28MM	4/2/18	Tritanium PL	cage appeared fractured in a follow-up x-ray
STRYKER ORTHOPAEDICS-CORK	11MM X 6DEG X 11MM X 28MM	3/12/18	Tritanium PL	Surgeon removed the inserter with interbody and the top 1/3 attached to the inserter, while the remaining 2/3 shattered in pieces in the patient's body. All pieces were removed and surgeon took additional fluoro to confirm all particles where removed. Surgeon completed surgery with a new device and completed the surgery successfully. There was a reported surgical delay of 1 hour 15 minutes.
STRYKER ORTHOPAEDICS-CORK	10MM X6DEG X 9MM X 28MM	3/12/18	Tritanium PL	cage was discovered fractured at the level of l4/l5 in an x-ray, post operatively
STRYKER ORTHOPAEDICS-CORK	11MM X 6DEG X 11MM X 28MM	3/9/18	Tritanium PL	the implanted cage had several points of fracture
STRYKER SPINE-US	10MM X 6DEG X 11MM X 28MM	3/7/18	Tritanium PL	cage deformed upon insertion
STRYKER CORPORAT	TRITANIUM CAGE	2/27/18	Tritanium PL	simply crumbled
STRYKER SPINE-US	9MM X 0DEG X 11MM X	2/13/18	Tritanium PL	final x-ray indicated the cage split
STRYKER SPINE-US	8MM X 6DEG X 9MM X	1/25/18	Tritanium PL	In Situ Collapse: l5/s1 surgery on (b)(6) 2017. At the three month post-operative appointment, the physician performed an x-ray and noticed a broken cage.
STRYKER SPINE-US	9MM X 6DEG X 11MM X 23MM	12/8/17	Tritanium PL	Cage main body fracture intra-op
STRYKER SPINE-US	11MM X 6DEG X 9MM X 28MM	11/21/17	Tritanium PL	In Situ Collapse

STRYKER SPINE-US	11MM X 6DEG X 9MM X 23MM	8/28/17	Tritanium PL - 07613327117356 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48950116	It was reported that; upon rotating cage the cage broke in half almost at the midline.
STRYKER SPINE-US	10MM X 6DEG X 9MM X 23MM	7/24/17	Tritanium PL - 07613327117417 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48950106	It was reported that the surgeon insertered implant into the disc space then attempted to rotate the cage for proper anatomical alignment and the back 1/3 part of the cage sheered off.

STRYKER ORTHOPAEDICS-CORK	10MM X 6DEG X 11MM X 28MM	7/10/17	Tritanium PL - 07613327118087 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955106	It was reported that; cage broke when impacting cage into disk space.
STRYKER ORTHOPAEDICS-CORK	12MM X 6DEG X 11MM X 28MM	7/10/17	Tritanium PL - 07613327118100 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955126	It was reported that; cage broke upon insertion to the disc space.

STRYKER SPINE-US	9MM X 6DEG X11MM X 28MM	6/13/17	Tritanium PL - 07613327118070 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955096	It was reported that during tlif procedure the cage broke apart into pieces while inserting.
STRYKER ORTHOPAEDICS-CORK	13MM X 6DEG X 11MM X 28MM	4/28/17	Tritanium PL - 07613327118117 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955136	It was reported that; wrong inserter was used by rep. Fracture of cage occurred. Another cage was implanted.

STRYKER ORTHOPAEDICS-CORK	10MM X 6DEG X 11MM X 28MM	4/10/17	Tritanium PL - 07613327118087 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955106	It was reported that the cage fractured during insertion.
STRYKER SPINE-US	9MM X 0DEG X 11MM X 28MM	4/5/17	Tritanium PL - 07613327117851 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48953090	Event Description It was reported that; upon implanting an interbody device the cage became twisted. The surgeon noticed it, removed the implant and a new cage was used successfully. Manufacturer Narrative Visual inspection; device history review; complaint history review; risk assessment; manufacturing records were reviewed for the corresponding lot and no relevant issues were identified. The returned cage was found not only twisted but also fractured. The most likely cause of the reported event was determined to be torsional overload when the surgeon tried to adjust the angle; misaligned

STRYKER SPINE-US	9MM X 0DEG X 11MM X 28MM	2/20/17	Tritanium PL - 07613327117851 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48953090	It was reported that; the cage broke during insertion and positioning of cage. The correct inserter (size 11) was allegedly threaded onto cage and implanted. There was no reported delays or adverse event occurred during surgery.
STRYKER SPINE-US	10MM X 0DEG X 9MM X 23MM	2/13/17	Tritanium PL - 07613327117295 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48950100	It was reported that the cage broke during spine surgery due to patient in pain. Additional device available for replacement of broken cage. No adverse consequences or delay. Sales rep need replacement. Update 1/24/2017: "surgery was bc of pain most likely¿anyways, the cage broke during insertion due to the surgeon using a rotation technique which is when you put in on side and rotate to its proper cranial/caudal position".

STRYKER SPINE-US	11MM X 6DEG X 9MM X 28MM	2/10/17	Tritanium PL - 07613327117981 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48954116	It is reported that the surgeon did a couple taps during insertion of the cage and tried to turn and steer the cage. The nose of the cage was in the disc space was under load and the rest of the cage was not in. When rotating and steering the cage, it gave way behind the nose and it broke into multiple fragments that did not fall in the patient cavity. All fragments were retrieved. Used 1mm smaller sized cage to complete the procedure (10mm) procedure was completed successfully. No adverse consequences of the patient reported.
STRYKER SPINE-US	8MM X 6DEG X 11MM X 28MM	11/28/16	Tritanium PL - 07613327118063 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955086	It was reported that; cage appear to collapse in situ.

STRYKER SPINE-US	9MM X 0DEG X 11MM X 28MM	11/14/16	Tritanium PL - 07613327117851 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48953090	It was reported that; while attempting to insert a cage, the cage broke into several pieces.
STRYKER SPINE-US	TRITANIUM PL 9MM X 28MM X6DEG - 11MM POS	10/10/16	Tritanium PL - 07613327118070 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955096	It was reported that; while inserting the device in a collapsed disc space the back of the implant fractured. The instrument to implant interface was misaligned about 15 degrees and wasn't straight vertical due to the anatomy. While the surgeon was malleting into disc space the implant fractured/sheared about 7mm from the proximal end into the teeth of the cage. There were no safety issues to the patient, so surgeon left the cage implanted. The broken piece was removed and a bone filler was used.

STRYKER SPINE-US	TRITANIUM PL 9MM X 28MM X6DEG - 11MM POS	8/15/16	Tritanium PL - 07613327118070 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955096	It was reported that the surgeon was doing a high s1 case and had trouble advancing the cage, the surgeon had to twist the cage to insert; while twisting the cage during insertion, the cage broke along the skinny part of the graft window (was not in the disc space). It appears that when twisting the cage, the nose got caught in the sacrum and the cage broke. The surgeon was performing a revision of a competitor's product. Same size cage was used to complete the procedure. No adverse consequences to the patient.
STRYKER ORTHOPAEDICS-CORK	TRITANIUM PL 9MM X 28MM X6DEG - 11MM POS	8/15/16	Tritanium PL - 07613327118070 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955096	It was reported that; the surgeon shaved the disc space to 9mm. The cage was used on the 11mm inserter. The rep confirmed the implant was on firmly. The surgeon was very cautious when hitting the inserter with the mallet. Upon insertion, the graft was inserted half way into the disc space and the graft broke while in the patient. 2/3rds of the graft that broke off into the patient was impacted and left inside the patient. The piece that was on the inserter will be returned. First time, the surgeon used tritanium and nothing was done out of the ordinary. He did not insert the graft under distraction.

STRYKER SPINE-US	TRITANIUM PL 7MM X 28MM X6DEG - 11MM POS	7/8/16	Tritanium PL - 07613327118056 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955076	Method: visual analysis; material analysis; device history review; complaint history review; risk assesment; result: the customer reported event of a posterior lumbar cage main body fracture intra-op was confirmed via visual insp and correspondence. Manufacturing records were reviewed for the corresponding lot and no relevant issues were identified. The submitted cage was found to have fractured in ductile overload during implantation. The observed elements were found to be consistent with what was listed on the drawing. No material or manufacturing defects were found. Conclusion: the plausible root cause of the reported event is likely due to the misaligned insertion force during cage
STRYKER SPINE-US	TRITANIUM PL 12MM X 28MM X6DEG - 9MM POS	6/28/16	Tritanium PL - 07613327117998 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48954126	It was reported that the doctor was inserting a cage into a disc space using a rotate and turn technique utilizing a custom inserter when the graft broke. He was under bilateral screw distraction at the time and had shaved the disc space to the corresponding cage height. The doctor left the broken segment in the space and back filled with bone.

STRYKER ORTHOPAEDICS-CORK	TRITANIUM PL 9MM X 28MM X6DEG - 11MM POS	4/27/16	Tritanium PL - 07613327118070 Posterior Lumbar Cage Company Name: Stryker Corporation Version or Model: 48955096	It was reported that the doctor was inserting the cage into the disc space. He was malleting the cage in and the cage split in half. Half the cage was in the disc space and half was still on the inserter. Normal steps were taken to prepare the disc space; shavers, paddles, and trials. After some time, the cage was able to be removed from the space, and the same size cage was inserted in without any problem, after distraction off the screws.
K2M, INC.	CASCADIA INTERBODY SYSTEM	11/30/17		That an interbody was not functioning as intended
K2M, INC.,	CASCADIA INTERBODY SYSTEM	9/15/17	6101-2103208N T12-G2	On 08. 18. 2017 it was reported to k2m, inc. That an interbody spacer had broken post-operatively.
K2M, INC.	CASCADIA INTERBODY SYSTEM	1/12/17		cage fractured during insertion and a portion of the implant remains in the patient. Surgery took place (b)(6) 2016.
