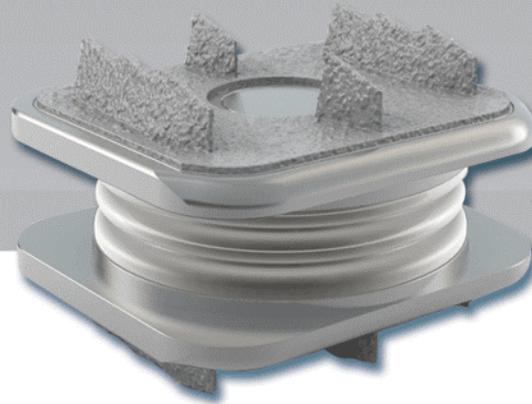
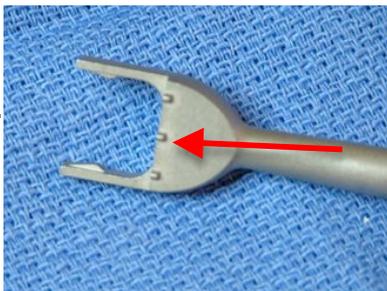


M6^C
artificial cervical disc

September 2010



M6-C Inserter “Shadow Keels” What are they, Why and Watch Out!



Shadow Keels.

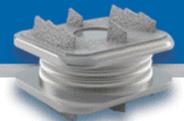
If you have ever wondered what the small “bumps” are on both sides of the M6-C Inserter, they are known as “Shadow Keels”. They provide a solution to a very specific set of circumstances during the implantation of the M6-C.

As you know, the flat surface of the Inserter impacts the anterior endplates of the M6-C to push the implant into position. In a disc space that is quite lordotic, it is possible for the anterior portion of the M6-C to very briefly open a bit wider than the broad flat surface of the Inserter. Without the Shadow Keels it is conceptually possible for the Inserter to slip in between the M6-C

endplates in these instances. The Shadow Keels have been carefully designed to add surface area in this instance so that the Inserter maintains good contact with the implant endplates while positioning continues without interruption or mishap.

The Shadow Keels basically do their job without it being obvious, so it is possible they have been involved in some of your cases without you or the surgeon being aware.

There is a particular set of circumstances however that you and your surgeons need to be aware of regarding the Shadow Keels.



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Fig 2



Fig 3

You will notice that the Shadow Keels align with the keels of the M6-C (Fig 2). This is so they will be able to follow the M6-C in the grooves made by the Chisel during implantation. However, looking at the Inserter and M6-C from the surgeon's perspective and not being aware of the Shadow Keels, it is possible to mistake or confuse them for the M6-C keels (Fig 3). This is only a potential problem if the surgeon does not carefully

watch the progression of the M6-C on x-ray during implanting.

If the surgeon relies only on an external visual reference of watching how far into the disc space the keels progress, based on the Chisel blade's location when it was placed, and the Shadow Keels are mistaken for the M6-C keels, this is a set up for the possibility of the M6-C to be positioned too far posterior.

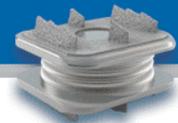
Follow the pictures below to see an example:



The Chisel has been placed and confirmed on x-ray. The surgeon mentally notes the relation of the Chisel blades to the anterior vertebrae.



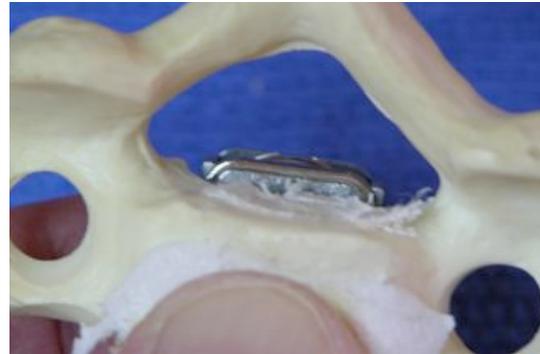
If we could see the coronal view, it might look something like this. Good position and placement.



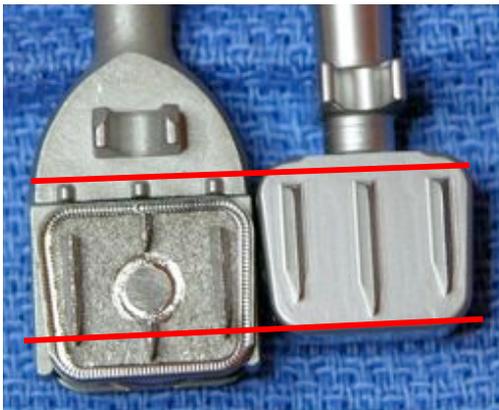
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If the surgeon mistakes the Shadow Keels for the M6-C keels and tries to visually match the location in the vertebrae, without checking on x-ray, the M6-C may be too far posterior.



In this example, looking from below the vertebral body, the result would be an implant beyond the posterior rim.



Even if the Shadow Keels are not placed quite as deep as the Chisel blades, the result will be an implant beyond the position obtained by the Chisel.

The obvious prevention to a potential result like this is to carefully follow the steps in the Surgical Technique Manual. The use of x-ray to guide the final positioning of the M6-C is a critical part of guaranteeing success and a great outcome.

Educate your customers on the reason for the Shadow Keels as well as how to avoid such a mistake.