

For the SQ.line® KERRISON several tests were performed to verify their safety and performance. The tests are described and appraised in the following sections:

### SQ.line® KERRISON bone punches

#### Jamming test

Five samples of three different SQ.line® KERRISONS and previous AESCULAP® KERRISONS each were tested on lamb spine with 50 repeated punches. The SQ.line® KERRISON showed no jamming during the entire test.

#### Manual cutting endurance test

Three samples of two worst-case SQ.line® KERRISONS and previous AESCULAP® KERRISONS each were used to cut lamb spine 25,000 times. All SQ.line® KERRISONS were perfectly functioning after the test cycles without repair and thereby showed an up to three times increased durability.

#### Destructive test

The required destructive force was measured for five samples of two worst-case SQ.line® KERRISONS and previous AESCULAP® KERRISONS each, biting on a metal plate. The SQ.line® KERRISONS withstood significantly greater forces on the cutting edge than the corresponding previous AESCULAP® KERRISONS.

#### Milk lubrication test

Three samples of the SQ.line® KERRISONS were lubricated with an emulsion of water and instrument milk. Afterwards, the samples were able to successfully punch a test card 50 times without jamming between the main part and the slider.

#### Performance test aged

Five samples of the most delicate SQ.line® KERRISON bone punch and three corresponding previous AESCULAP® KERRISONS were compared. After aging the SQ.line® KERRISONS by 500 reprocessing cycles they successfully passed all defined test criteria for the wear parts. The SQ.line® KERRISON outperformed the previous AESCULAP® KERRISONS.

#### Gloss value measurement

The gloss values of two new and five aged SQ.line® KERRISONS were measured on three defined areas from two different angles each. The results were compared to the values of uncoated AESCULAP® KERRISONS. The processing had no significant

influence on the reflection behavior. The Noir® plus coating reduced reflections on the slider by 70 % to 86 %, on the main part by 47 % to 63 % and on the handle by 19 % to 76 % depending on the direction of measurement.

#### Handle comfort evaluation report

The SQ.line® KERRISON handle was compared in terms of comfort during use to its predecessor and one of its competitor's handle. It is based on the visualization of prevailing surface pressure distributions during the actuation by means of pressure measuring foil. The SQ.line® KERRISON showed smaller areas of high surface pressure and a more homogeneous pressure distribution.

#### Usability test with CSSD personal

The usability test with neurosurgeons was performed to validate multiple customer requirements in terms of the performance and the ergonomics of SQ.line® KERRISON. The test was performed with 12 neurosurgeons within a simulated clinical environment. The performance and the ergonomic properties were rated positive.

### SQ.line® KERRISON racks

#### SQ.line® KERRISON shake test

The SQ.line® KERRISON shake test was performed to investigate the resistance of the Noir® plus surface to scratches in comparison with the existing bone punches. For this purpose a sieve basket and a SQ.line® KERRISON rack, both containing bone punches, were fixed on a vibrating plate. It could be demonstrated, that the scratching of surface is strongly reduced with the use of the SQ.line® KERRISON racks.

#### Usability test of SQ.line® KERRISON Reprocessing Racks

A usability test for the SQ.line® KERRISON racks was performed to validate the realization of multiple user needs and other requirements. Ten AESCULAP® employees who have knowledge in storage and reprocessing of surgical instruments and are familiar with general OR techniques and OR environment were interviewed. All users rated the usability of the racks positive.