TechNoles Exactech® Bone Quality Indenter
Mock 510(k)

Company: TechNoles

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Proprietary Name: TechNoles Exactech® Bone Quality Indenter

Common Name: Bone Indenter

Classification Name: Orthopedic Manual Surgical Instrument, Class I

Device Description:

The device that we are proposing is a handheld indenter that will extend into the trabecular bone of the humerus at the site of implantation for the patient. There are three main components to the device, these being the housing with external and internal stopping arms, the rod with indenting tip on one end and syringe pull system on the other, and the spring that generates the force to be applied. The housing will be a stainless-steel body similar in dimensions to a mechanical pen with internal arms to prevent the rod from extending too far and external arms to hold the device in place against the cortical bone and ensure that the tip is lined up properly. The rod will contain the pointed end that moves into the bone when the spring is released as well as the pulling mechanism to compress the spring before use. A notch on the rod will compress the spring as the arm is pulled from the opposing end, and the mechanism will lock in the ready position. The device will then be released, and the spring will shoot the rod down the casing and cause the indenter tip to penetrate the surface of the bone. A length scale will be engraved into the steel of the device that is used to measure the depth of the indentation under the pre-calculated force of the spring.

The indenting tip of the rod and mechanical stopping arms are the only parts that will contact the patient's tissue and both components will be stainless steel. The tip will contact the spongy, trabecular bone as it applies the force on the bone. The mechanical arms will be positioned to

contact the cortical bone to prevent the indenter from slipping out of place and shooting into the incorrect parts of the bone, causing damages that further complicate this procedure.

Legally Marketed Devices to Which Equivalence Is Claimed:

- Exactech® Equinoxe® Preserve Stem (K162726)
- Osteotomes (K952193)
- Mallet (K871195)

The TechNoles Exactech Bone Quality Indenter is similar to the devices mentioned in the sense of material, biocompatibility, and sterilization process after use in the operating room. Predicate devices mentioned are all stainless-steel devices used during orthopedic procedures and are similar in medical instrumentation to our proposed device. The proposed device will be used on the humeral bone that implantation will occur at to measure the quality of the patient's bone at that spot. The proposed device will aid the operating surgeon in determining the type of implant needed for the shoulder arthroplasty.

Predicate Comparison

Description	TechNoles Exactech Bone Quality Indenter	Predicate Device (Equinoxe Preserve Stem)	Predicate Device (Osteosomes)	Predicate Device (Mallet)
Use	Measure Humeral Bone quality	Shoulder implant into Humeral Bone	Cutting and shaping bone in orthopedics	Forcibly altering bone in orthopedics
Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Size of tip	Diameter range 4mm - 6mm	Diameters range 6mm - 15mm	Diameters range 1mm - 6mm	Face Diameter range 25mm-40mm
Sterility	Sterilized after each use	Individually packed and sterilized	Autoclave sterilization after each use	Sterilized after each use

Table. 1

Indications for Use

The TechNoles Exactech Bone Quality Indenter is intended to quantitatively determine the quality of a patient's bone during a total shoulder arthroplasty. In order to avoid an implant failure and harm to the patient, surgeons will use this device to estimate the suitability of

stemless implants in order to increase the success of the procedures. The device will ensure safe practices and provide numerical evidence that can be used in future practice.

Contradictions: The TechNoles Exactech Bone Quality Indenter is not intended for the acquisition of bone quality data and is meant to only be used by qualified medical personnel who are qualified to create and diagnose the indentation and bone quality.

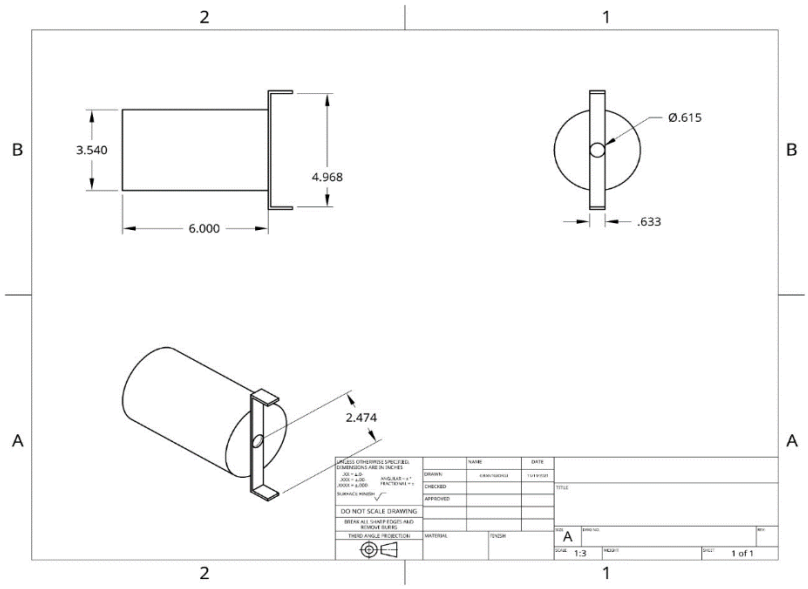
Summary of Technological Characteristics

- **Indications for Use:** The TechNoles Exactech Bone Quality Indenter is intended to quantitatively determine the quality of a patient's bone during a total shoulder arthroplasty and is demonstrated to be safe and effective.

- **Materials:** The materials that compose the TechNoles Exactech Bone Quality Indenter are manufactured from similar materials as the predicate devices that have been demonstrated to be safe and effective when used in direct contact with tissue in equivalent uses.

- **Design Features and Dimensions:**

Housing Schematic



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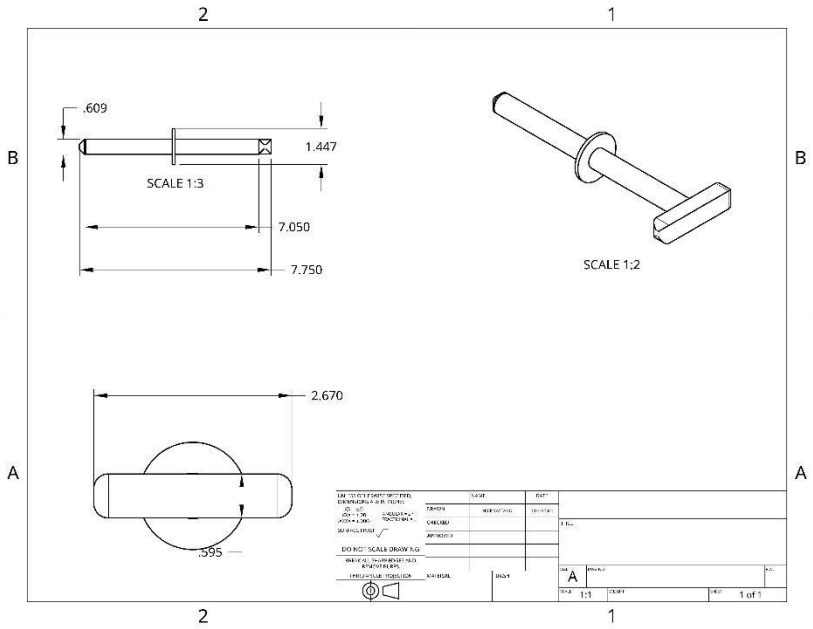
Indenter and Rod Schematic



- **Sterilization:** The materials that compose the TechNoles Exactech Bone Quality Indenter are manufactured from similar materials as the predicate devices that have been demonstrated to be safe and effective through equivalent sterilization methods. Both devices are sold as sterile and withstand similar temperatures. Since these devices are manufactured from similar materials and have similar design features, the TechNoles Exactech Bone Quality Indenter is safe and effective for equivalent shelf life.

Non-Clinical Testing

The proposed device has been tested using a series of sawbone blocks. The device measured the force applied to the sawbone blocks and the corresponding density. The performance of the device was determined by placing the device against the various density blocks and taking readings. This data was then compared to the blocks to determine the accuracy of the device.

Wear was then tested by using a calibrated device on sawbones repeatedly. The device was used to take measurements more than fifty times. The results were then compared to the sawbone

densities to ensure the device does not experience loss of strength in the spring resulting in inaccurate measurements. Additionally, the device was then examined after each measurement to look for wear or scarring on the indenter head.

The force applied by the indenter at each density was recorded by applying the device to a scale. The scale was read at each density to determine the total force applied at the various densities.

Potential damage to bones was examined by taking measurements of animal bone samples. These came from meat cuts from a butcher shop. The device took the measurements, and the bone was examined for scarring or damage. The measurements were taken multiple times per bone.

Animal Testing

Animal testing for the proposed device has undergone similar testing to the dual-energy x-ray absorptiometry in animals. Specifically, the animal tests have been conducted and include the measured bone mineral density intraoperatively in small-sized animals (rodents) and large-sized animals (porcine). In small animals the device was observed for efficient and accurate bone characterization. Bone mass was measured before implantation and after metallic implantation in large-sized animals, as well as analysis of stem failure rates in comparison to density data post operation. The objective of the study was to determine if the use of the proposed device results in successful densitometry in test animals. The endpoint of this study was to collect specific bone characterization data including force applied, indentation depth and resulting bone density values.

Clinical Testing

Clinical testing for the proposed device has undergone similar testing conditions to the predicate devices. The objective of the clinical testing is to determine whether the proposed device accurately measures bone density intraoperatively and minimally invasive. Individual case studies and data comparison methods will be used to analyze efficacy of the device. Detailed description of the issues and analyzing whether the issues have been resolved will be evaluated both immediately and over the long-term. For the proposed device, data will be analyzed to determine if the bone that has been characterized correlates with a successful long-term shoulder arthroplasty. Sponsors of testing will follow the regulations of review boards and informed consent, and clinical testing will result in a Certificate of Compliance upon completion.

Substantial Equivalence Discussion

Based on consideration of indications for use, technological and mechanical characteristics, as well as the results of testing, it was concluded that the TechNoles Exactech Bone Quality Indenter demonstrates substantial equivalence to the referenced predicate devices.