Drop Test Simulation of Sterilization Tray

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Abstract: **Medical product designers are faced with a number of unique business and design issues. Drop/impact tolerance, or the capacity to safely survive an accidental drop, is becoming a more important factor of portable product durability. In this paper we focused on drop test of sterilization tray to understand the displacement of instruments placed inside it and variation of stress. Drop test performed using 6 orientations. Numeric simulation helps in the quality assurance of medical equipment. We can use simulation tools to forecast function and perform quality checks on products. To generate mesh the preprocessor hypermesh version 19 was used. FE model preparation used 2D shell mesh, 3D hex mesh, 3d tetra mesh. The FE simulations will be run in the ABAQUS/ Explicit computer software, which is designed for dynamic impact problems. From the simulation energy plots has been obtained. The main purpose of this paper is satisfied that is the instruments placed inside it are not falling out. It has been detected that from the stress variation no stress exceeds the yield stress of material.**

Keywords — FEA, Drop test, Hypermesh, Abaqus.

I. INTRODUCTION

The medical industry today is very turbulent and competitive, with changes occurring virtually daily. Designers must create new items fast and at a low cost while maintaining a high level of quality and performance. One of the leading manufacturers of medical devices developed a sterilization tray with locking mechanism such that the instrument held inside should not touch each other and should not fall on floor after impact on floor. Sterilization tray are plastic or metal containers used to hold and safeguard surgical devices such as scalpels, scissors, saws, cautery, retractor, forceps and clamps during the sterilizing procedure. They generally consist of an interlocking tray and lid secured to the base by means of a latching mechanism. Pins, holding clamps, cradles and silicon mates are used as dividers to assist secure the instruments in tray. These instruments are held in place by these tools throughout sterilization, storage and transportation preventing instruments breakage and damage. If the sterilizing tray fall from table or from operating room personnel hands on the floor then the instruments inside should not be displaced or should not be fall on floor because falling instruments leads to increased operating time and extra resources to sterilized the instruments hamper the end result of the surgery. So, there is expectation is that instruments should not fail due to accidental drop of sterilizing tray.

A component falls freely during a drop test. Typically, it is done to see if a product can withstand loads that are introduced suddenly. Drop test is one of the functional test requirements of sterilization tray before being sold for actual usage. Drop tests can be used to guarantee that handheld product and equipment are durable. Physical drop testing on prototypes have long been used to assess the integrity and dependability of a product's packaging [1]. Generally, these tests are qualitative. This method performed many numbers of times to evaluate ability of component to resist the impact. Those tests can provide results but it is very costly, time consuming and required large amount of efforts. Also testing at the end of the product development causes high costs and delay and providing little feedback to improve the product. Furthermore, due to space constraints for installing equipment and sensors, the mechanics of failures and their causes are often difficult to differentiate in experiments.

So, from above disadvantages of experimental method, attention has shifted to the finite element approach. It is preferable to use numerical simulation to study the component's mechanical properties. This would result in a reduction in development time, since the FE-simulation can give essential information. The information collected can be utilized to visualize the impact results using a computer simulation approach with FEM. The simulation can record any mechanical information on the analyzed entity at each time step.

Harrysson [2] investigated the different issues involved in drop test simulation of a cellular phone, an explicit time integration scheme was used. A hypo elastic material is used. The elements used foe simulation are second order

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tetrahedron elements and first order hexagon elements. Gu and Jin [3] have carried out Drop Test Simulation and DOE Analysis for Design Optimization of Microelectronics Packages. An innovative technique was explained in detail based on finite element modelling and design of experiment (DOE) to study the influence of all conceivable important parameters. Wu and Briant [4] have described the use of finite element analysis (FEA) in the development and study of medical device failures. The paper goes over some of the key procedures and concerns involved in using the finite element method to design and analyze devices. Zhou et al. [5] had analyzed drop test of typical portable electronic devices. This study examines how commonly used portable electronic gadgets respond dynamically to drop impact loads. Wu et al. [6] have analyzed vibration of medical devices by a finite element analysis (FEA) model calibrated with test data. Based on design criteria and static testing, a FEA model of the AED is created using ANSYS in this study. Pan et al. [7] developed a reliable method for measuring TFT-LCD display performance under drop conditions. LS-DYNA, a commercially available FEM package, is used to calculate impact acceleration and dynamic strain upon that TFT-LCD panel and mold frame under drop test conditions.

II. Problem Formulation

If the sterilization tray fails to hold the instrument insides they will fall on the floor. Falling tend have greater impact on more complex and delicate instruments. So, to ensure safeguard of instruments inside the locking mechanism should work properly. For this purpose, there is need to conduct drop test simulation of sterilization tray. The main problem in this thesis to investigate the FINITE ELEMENT SIMULATION of free fall of sterilization trays such that tray should not unlock to prevent displacement of instrument placed inside. The data gathered can be used to visualize the impact results using a computer simulation approach with FEM. Fig. 1 shows the assumed drop orientations for tray.

Following are the drop orientations of the tray-

1.bottom surface of the tray.

2.1st adjacent bottom edge of the tray.

3.2nd adjacent bottom edge of the tray.

4.1st bottom corner of the tray.

5. 2nd diagonally bottom corner of the tray.

6.bottom surface from twice the specified height.

The inclination is 30 degrees when dropping on edge and corners.

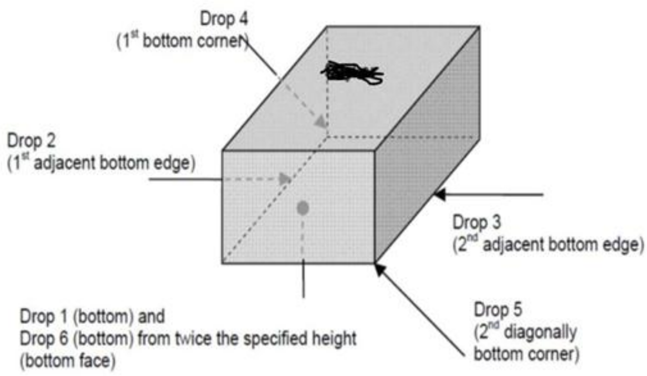

Fig -1: Drop test orientations

III. Methodology

A. TRAY INFORMATION

The shape of sterilization tray is rectangular like a rigid container. Both the bottom and upper surfaces are perforated to allow sterilizing agent to pass from outside the tray to the devices inside.

It is having handles and a lid secured to the base by means of latching mechanism. To help secure the instruments dividers and tools are available including pins, holding clamps and silicon mats. The tray is filled with instruments. The idea of tray is that to hold that instrument securely.

B. CAD Data

The geometry used are shown in Fig. 2. The geometry file is of stp type. A geometry cleanup was implemented to avoid unnecessary complications when building mesh. In geometry cleanup the possible errors from the importing the stp file are erased and some lines that are no interest for the output of the drop test analysis are eliminated.

C. Finite Element Modelling

The whole geometry of sterilizing tray consists of an outer body, middle tray, surgical instruments and their supports. A lot of factors must be considered while choosing an element type for simulation. One of the most essential factors is the ease of mesh production, as well as

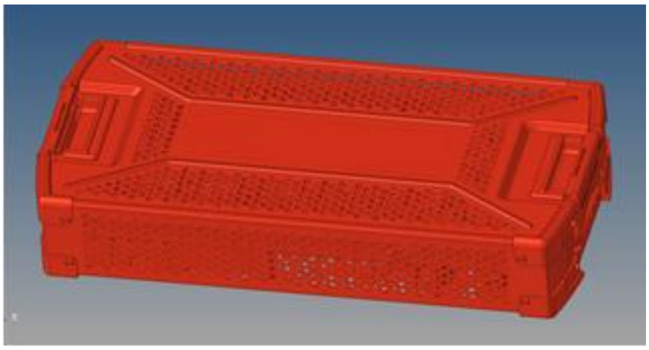

Fig. -2: CAD model

the accuracy of the simulation element [2]. The mesh generation for the geometry described in Section 3.2 is made in hypermesh version 19, a preprocessor developed

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and distributed by Altair. The outer plates and middle tray are meshed with 2-D Quad element. The instruments are meshed with 3D tetra element and their supports are meshed with 3D hexa elements. Several approaches were used during the modelling and validation process to ensure the correctness and dependability of the finite element simulation results. Because of their increased rigidity, the triangular element and pentagonal solids were typically avoided. Fig. 3, fig.4 and fig.5 final mesh of the tray.

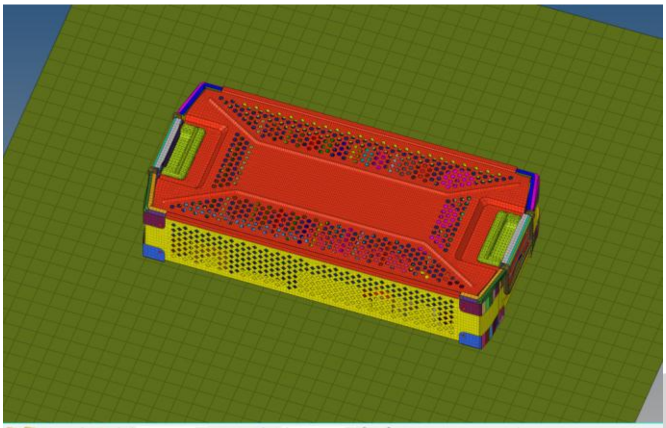

Fig. -3: overview of mesh

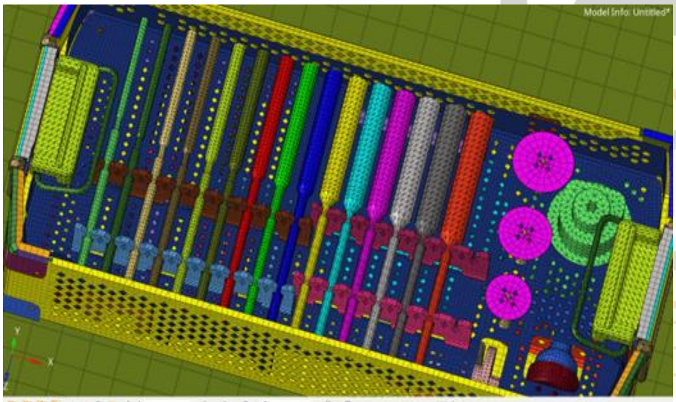

Fig. -4: overview of mesh

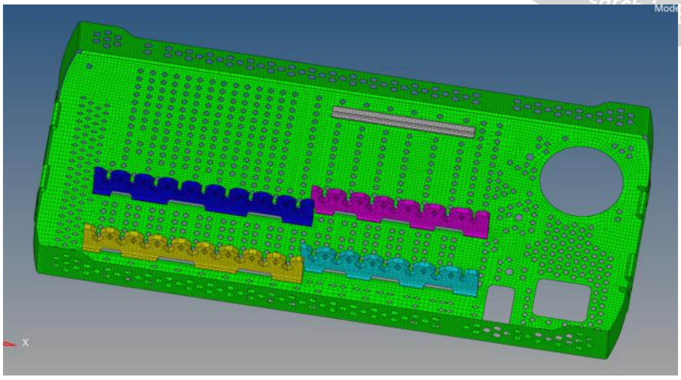

Fig.-5: overview of mesh

D. Material Data

After the meshing it is important to give thickness to 2 D shell elements. And is important to consider the material properties also. In this paper, the following characteristics typically describe material models: density, Young's modulus, density. Table 1 shows the material list that is assigned to mesh.

E. Methodology of Computer Simulation

Computer simulation based on FEM has been widely used in the industry for the past 40 years, thanks to the development of the finite element method (FEM) and the use of high-speed computers. In the transient analysis by FEM, there are two basic algorithms for time integration: implicit and explicit formulation [8]. Understanding the characteristics of these algorithms will made analysts in selecting the most appropriate algorithm for a given situation.

Table -1: Material Properties

Material	Young' modulus (MPa)	Density (g/cc)	Poisson ratio
B138 PEEK	4318	1.40E-09	0.42
SS	2100000	7.85E-09	0.3
B324 Polypropylene	1450	9.00E-10	0.41
B323-TPE	2760	0.785E-09	0.44
B1001 PEEK	4300	1.23E-09	0.42
B341 HTV Silicon 80	4.51	2.33E-09	0.44
B341 HTV Silicon 81	4.53	2.33E-09	0.44
B341 HTV Silicon 82	4.56	2.33E-09	0.44
17-4 PH-SS	190000	7.75E-09	0.27
455-PH-SS	190000	7.75E-09	0.28
Propyulux	2160	0.9E-09	0.35

The governing equation of a dynamic system can be expressed as [8]

$$M\ddot{x} + C\dot{x} + kx = \mathrm{P} \quad \ldots\ldots\ldots\ldots (1)$$

For a transient analysis, a dynamic process is divided into time steps. Time step integration is an algorithm to predict an unknown state, at time step t + dt from a known state at moment t. The entire dynamic process is calculated, in this way, step by step. For explicit formulation, a central difference time integration method is used and equation (1) can be written as when the equilibrium state is considered at moment t

$$M\ddot{x}_t + C_{\dot{x}_t} + kx_t = P_t \quad \ldots\ldots\ldots\ldots (2)$$

In contrast, implicit formulation considers its state of equilibrium at time t + Δt and the governing equation can be written as

$$M\ddot{x}_{t+\Delta t} + C\dot{x}_{t+\Delta t} + kx_{t+\Delta t} = P_{t+\Delta t} \quad \ldots\ldots\ldots\ldots (3)$$

An impact has short duration. To able to crack high frequency response a very short time step has to be used. contact will occur during impact and this will introduce nonlinearity in analysis. a large time step will cause a large contact force at contact interface, which will result in local distortion and analysis failure [2]. So, from above reasons most suitable approach is to be explicit time integration. There are several explicit commercial finite element codes on the market, including Abaqus/CAE 6.14, which was used in this study.In this model contact uses as surface-to-surface contact between the holding clamp and instruments. Contact pair card is used for that.

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**Contact Pair, interaction=FRIC_01-STEP1, mechanical constraint=KINEMATIC, cpset=FRIC_01-STEP1-1-1*
S69, M69

F. Boundary Conditions

The simulation was set up in such a way that a one-meter drop test could be carried out. The sterilizing tray is just above the ground at the start of the simulation, with an initial velocity of 1 meter per second. It is possible to calculate the initial velocity based on energy conservation.

$$\frac{1}{2}mv^2 = mgh \quad \ldots\ldots\ldots (4)$$

$$v = \sqrt{2gh} \quad \ldots\ldots\ldots (5)$$

So, we get the velocities as 4429.44 mm/sec and 6264.18 mm/sec for 1m and 2m enhanced height respectively.
The floor is modelled as a rectangular mesh with rigid properties.

G. simulation results

In the paper, six different drop cases defined by different drop orientations are simulated to thoroughly investigate the displacement of instruments placed inside the sterilization tray.
They are bottom, 1st adjacent to bottom, 2nd adjacent to bottom,1st bottom corner, 2nd diagonally bottom corner and twice the height of drop bottom. For each case, and for each material analytical results can be reported and discussed in terms of displacement and stress distributions. In this paper, there is not enough space to list every result term for each material, so we focus on only our interested areas that is the middle tray and instruments support as an example in what follows.
The Energy Summary shows plot of internal energy, kinetic energy, total energy as shown in Fig. 5 to 7. From plot the potential energy is converted into kinetic energy during drop. This kinetic energy will start reducing as it comes in contact with the surface and converted into internal energy as shown in fig. the time where kinetic energy reach zero it is considered as contact time. Hence stress in component will be at its peak. Therefore, result of drop test are noted at this particular time.
Fig. 8,9,10 shows the displacement of component. Table 2 gives the max displacement of each instrument and Table 3 gives the maximum stress in the component.

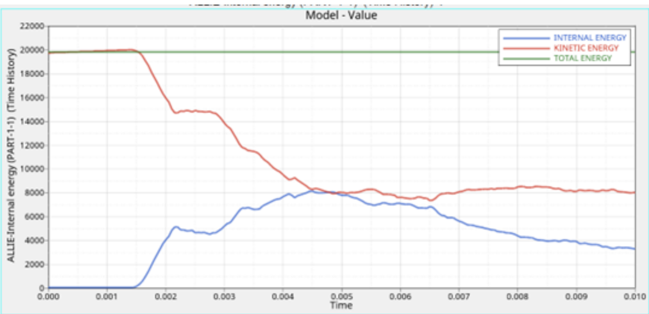

Fig. -6 Energy plot (drop1)

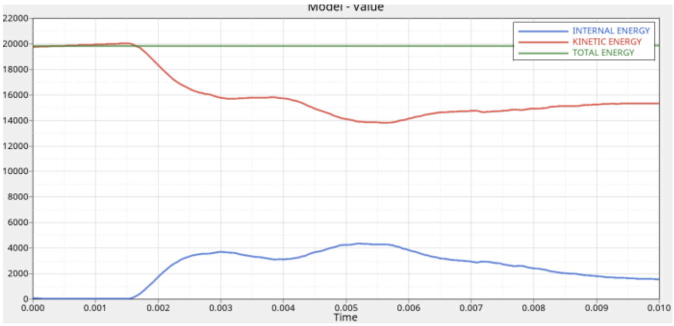

Fig. -7 Energy plot (drop2)

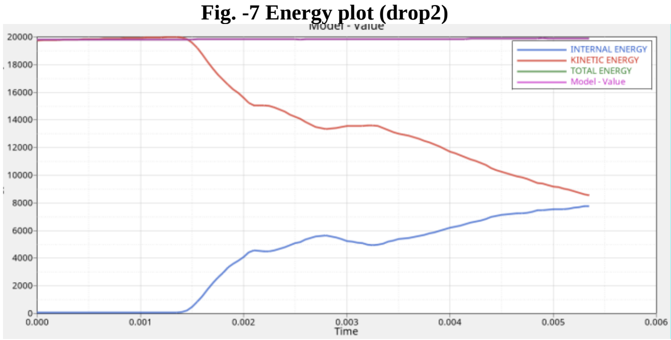

Fig. -8 Energy plot (drop3)

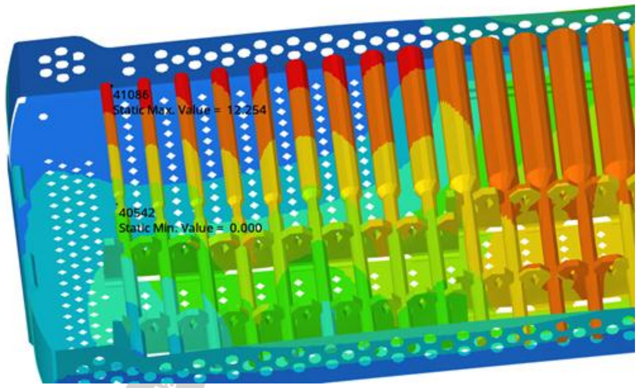

Fig. -9 displacement (drop1)

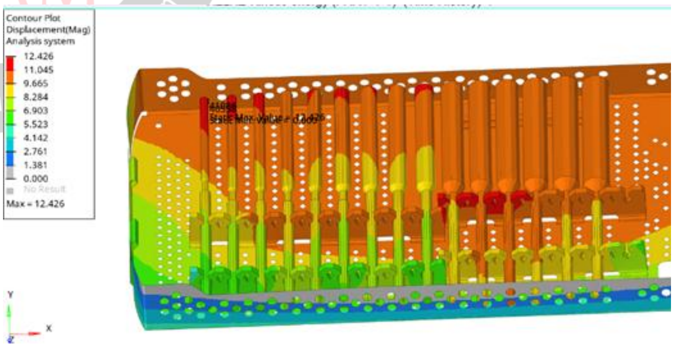

Fig. -10 displacement (drop2)

Fig. 12 to 17 shows the stress distrubution in tray for each drop respectively. From the stress distribution, the maximum stress is occuring at the corner of slots provide for the fitting of supports. There is need to provide fillet at corner.

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Fig. -11 displacement (drop3)

Table -2: Maximum Displacement of Tray

Orientation	Max displacement(mm)
Drop 1	12.2
Drop 2	12.4
Drop 3	10.4
Drop 4	22.1
Drop 5	20.4
Drop 6	14.0

Table-3: maximum stress in materials

Orientation / material	Drop 1	Drop2	Drop 3	Drop 4	Drop 5	Drop6	Yield strength
PH_SS_17-4	1059	830	972.2	409.4	433.82	1219.94	1345
HTV SILICON	8.3	7.4	6.7	4.8	4.60	13.03	145

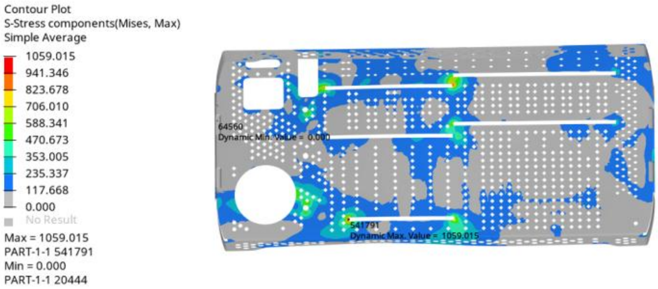

Fig. -12 stress distribution in tray (drop1)

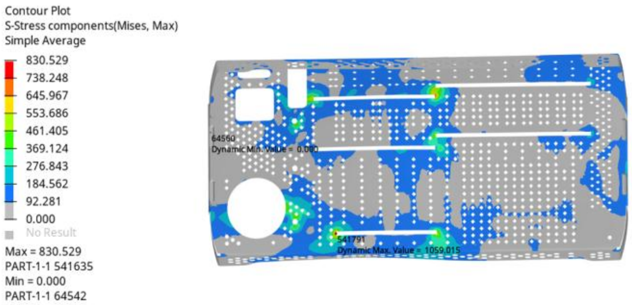

Fig. -13 stress distribution in tray (drop2)

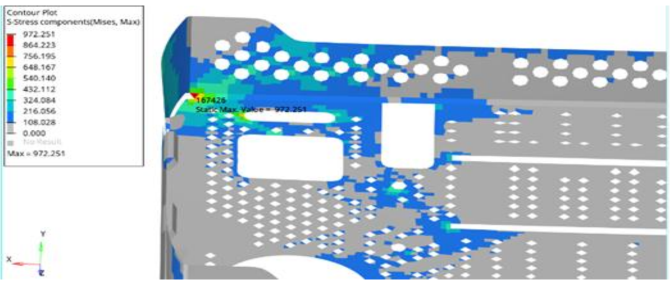

Fig. -14 stress distribution in tray (drop3)

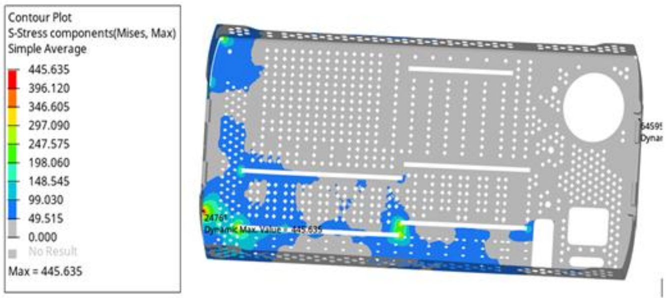

Fig. -15 stress distribution in tray (drop 4)

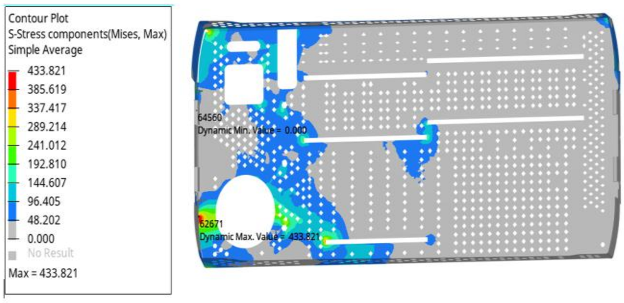

Fig. -16 stress distribution in tray (drop5)

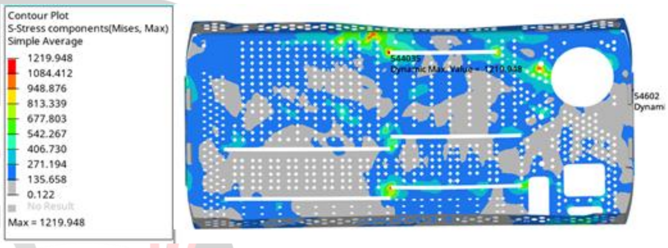

Fig. -17 stress distribution in tray (drop6)

IV. CONCLUSION

In this study, an advanced analytical simulation of the drop test of a sterilization tray was performed on software hypermesh and abaqus are used to perform drop test simulation. Looking at simulation we conclude as follows-

1. for all drop of tray, we can say that the not a single instrument is falling out from tray and also, they are not in contact with each other.
2. From the energy plots, as we can see that internal energy produced is almost same as the kinetic energy.
3. Total energy is remaining constant throughout the process, the law of conservation of energy is satisfied
4. The result of stress shows that in no case stresses exceeds that yield stress value of material. Considering this analysis, it is safe to use.

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